UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: April 4, 2022

Subject: Efficacy Review for
DS-6640, EPA Reg. No. 6836-385 - Primary, A570
E-Submission # 68095, Action code: 00325713
DS6809, EPA Reg. No. 6836-388 – Secondary, A570.1
E-Submission # 68096, Action code: 00325712

From: Tahirah Burford
Efficacy Branch
Antimicrobials Division (7510P)
Date signed: March 14, 2022

Thru: Sophie Nguyen
Efficacy Branch
Antimicrobials Division (7510P)
Date signed: April 3, 2022

To: Perri Moeller / Steven Snyderman, PM 33
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Arxada, LLC

Formulation from the Label:

DS-6640, EPA Reg. No. 6836-385

Active Ingredients	**% by wt.**
Hydrogen peroxide….	1.22%
Other Ingredients	98.78%
Total	100.00%

DS6809, EPA Reg. No. 6836-388

Active Ingredients	**% by wt.**
Hydrogen peroxide….	1.22%
Other Ingredients	98.78%
Total	100.00%

I. BACKGROUND

Product Description (as packaged, as applied):

DS-6640, EPA Reg. No. 6836-385 - Primary: RTU Spray
DS6809, EPA Reg. No. 6836-388 – Secondary: RTU Towelette

Submission type: Label amendment

Currently registered efficacy claim(s): Hospital and healthcare one-step disinfectant, non-food contact sanitizer, mildewstat, and deodorizer.

Requested action(s): Add disinfection claims against Adenovirus Type 5, Measles virus, and Canine Parvovirus. In addition, electrostatic spray directions for use are proposed. All efficacy data to support these claims was generated by evaluating DS-6640 (EPA Reg. No. 6836-385). Registrant is citing the virucidal data set from DS-6640 to DS6809 (EPA Reg. No. 6836-388).

Documents consider/ed in this review:

- Cover Letter from applicant to EPA dated 23 September 2021
- Data Matrix (EPA Form 8570-35) dated 23 September 2021
- 6 efficacy studies (MRID 51683401 - 51683406)
- Proposed label for EPA Reg. No. 6836-385 dated 23 September 2021
- Proposed label for EPA Reg. No. 6836-388 dated 23 September 2021
- Confidential Statement of Formula (EPA Reg. No. 6836-385) dated 16 September 2021
- Confidential Statement of Formula (EPA Reg. No. 6836-388) dated 16 September 2021

II. DIRECTIONS FOR USE

EPA Reg. #6836-385:

"DISINFECTION [/ *VIRUCIDAL] DIRECTIONS:

Spray 6 - 8 inches from surface[2], until surfaces are thoroughly wet. Do not breathe spray. Treated surfaces must remain visibly wet for 3 minutes. {Note to reviewer: if using reduced contact time for SARS-CoV-2, the following sentence will be required:} [For SARS-CoV-2, treated surfaces must remain visibly wet for 1 minute.] {Note to reviewer: if using reduced contact time for Measles Virus, the following sentence will be required:} [For Measles Virus, treated surfaces must remain visibly wet for 30 seconds.] {Note to reviewer: for products making claims against Canine Parvovirus, the following sentence will be required:} [For Canine Parvovirus, treated surfaces must remain visibly wet for 10 minutes.] Wipe dry with a clean cloth, sponge, mop or towel, or allow to air dry.."

EPA Reg. #6836-388:

"[TO CLEAN AND DISINFECT:] {OR} [CLEANING/ DISINFECTION / VIRUCIDAL* DIRECTIONS:]

For the market label, choose one statement from Option Set A and one statement from Option Set B:
Option Set A

1. Wipe surface[1] with [wipe] [towelette] [cloth] [sheet] until surface is visibly wet.
2. Use enough [wipes] [towelettes] [cloths] [sheets] to thoroughly wet surfaces.
Option Set B
1. Surface1 must remain visibly wet for 3 minutes. {Note to reviewer: if using reduced contact time for SARS-CoV-2, the following sentence will be required:} [For SARS-CoV-2, treated surfaces must remain visibly wet for 1 minute.] {Note to reviewer: if using reduced contact time for Measles Virus, the following sentence will be required:} [For Measles Virus, treated surfaces must remain visibly wet for 30 seconds.] [Let [permit] surface to [air] dry.]

2. Keep surfaces1 visibly wet for 3 minutes. {Note to reviewer: if using reduced contact time for SARSCoV-2, the following sentence will be required:} [For SARS-CoV-2, treated surfaces must remain visibly wet for 1 minute.] {Note to reviewer: if using reduced contact time for Measles Virus, the following sentence will be required:} [For Measles Virus, treated surfaces must remain visibly wet for 30 seconds.] [Let [permit] surface to [air] dry.]

3. [Use enough [extra] wipes to] keep surfaces1 visibly wet for 3 minutes. {Note to reviewer: if using reduced contact time for SARS-CoV-2, the following sentence will be required:} [For SARS-CoV-2, treated surfaces must remain visibly wet for 1 minute.] {Note to reviewer: if using reduced contact time for Measles Virus, the following sentence will be required:} [For Measles Virus, treated surfaces must remain visibly wet for 30 seconds.] [Let [permit] surface to [air] dry.]

4. Allow surface[1] to remain visibly wet for 3 minutes. {Note to reviewer: if using reduced contact time for SARS-CoV-2, the following sentence will be required:} [For SARS-CoV-2, treated surfaces must remain visibly wet for 1 minute.] {Note to reviewer: if using reduced contact time for Measles Virus, the
following sentence will be required:} [For Measles Virus, treated surfaces must remain visibly wet for 30 seconds.] [Let [permit] surface to [air] dry.]

5. [Wipe surface and] let surface1 [it] remain visibly wet for 3 minutes. {Note to reviewer: if using reduced contact time for SARS-CoV-2, the following sentence will be required:} [For SARS-CoV-2, treated surfaces must remain visibly wet for 1 minute.] {Note to reviewer: if using reduced contact time for Measles Virus, the following sentence will be required:} [For Measles Virus, treated surfaces must remain visibly wet for 30 seconds.] [Let [permit] surface to [air] dry.]."

III. STUDY SUMMARIES

1.	**MRID**	51683401	**Study Completion Date:**	12/05/2019
Study Initiation Date:		11/13/2019		
Study Objective		Disinfectant – virucidal		
Testing Lab, Lab Study ID		Analytical Lab Group-Midwest; Project #A28801		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Human Adenovirus type 5		
Indicator Cell Culture		A-549 (human lung carcinoma) cells		
Test Method		ASTM International E1053-20 “Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces; Protocol # LZ01110619.ADV		
Application Method		RTU Trigger Spray		

Test Substance Preparation	**Name/ID**	DS6640					
	Lots ☐ 1 ☐ 2 ☒ 3	Lot 6079-148; 1.16% Hydrogen Peroxide Lot 6079-148-B; 1.16% Hydrogen Peroxide Lot 6079-150; 1.16% Hydrogen Peroxide					
	Preparation	Tested concentration: LCL Tested Dilution: RTU Diluent: None					
Soil load		5% FBS					
Carrier type, # per lot		Glass Petri dishes (100 x 15 mm); 3 carriers (1 dried virus film per test substance batch)					
Test conditions		**Contact time**	3 minutes	**Temp**	22.0 °C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Relative Humidity was not provided					

2.	**MRID**	51683402	**Study Completion Date:**	10/31/2019
Study Initiation Date:		10/16/2019		
Study Objective		Disinfectant – virucidal		
Testing Lab, Lab Study ID		Microbac Laboratories; Project # 163-918		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Measles Virus, Strain: Edmontson, ATCC VR-24		
Indicator Cell Culture		Vero cells, Source: ATCC CCL-81		
Test Method		ASTM International E1053-20 “Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces; Protocol # 163.1.09.13.19		
Application Method		RTU Trigger Spray		
	Name/ID	DS6640		
	Lots ☐ 1 ☒ 2 ☐ 3	Lot 6074-166; 1.20% Hydrogen Peroxide Lot 6074-167; 1.19% Hydrogen Peroxide		
	Preparation	Tested concentration: LCL Tested Dilution: RTU Diluent: None		
Soil load		5% FBS		
Carrier type, # per lot		Glass Petri dishes (100 x 15 mm); 1 carrier per lot		
Test conditions		**Contact time** 30 seconds	**Temp** 21°C	**RH** 42%
Neutralizer		MEM + 1% Newborn Calf Serum (NCS) + 0.5% Polysorbate 80 + 0.5% $Na_2S_2O_3$ + 1% NaHCO3 + 2% HEPES + 0.1% Catalase		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		None		

3.	**MRID**	51683403	**Study Completion Date:**		12/05/2019		
Study Initiation Date:		08/28/2019					
Study Objective		Disinfectant – virucidal					
Testing Lab, Lab Study ID		Analytical Lab Group-Midwest; Project #A28414					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Canine Parvovirus, ATCC VR-2017, Strain Cornell					
Indicator Cell Culture		A-72 (canine tumor)					
Test Method		ASTM International E1053-20 “Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces; Protocol # LZ01080719.CPV					
Application Method		RTU Trigger Spray					
Test Substance Preparation	**Name/ID**	DS6640					
	Lots **☐ 1 ☒ 2 ☐ 3**	Lot 6079-028: 1.16% Lot 6079-029: 1.16%					
	Preparation	Tested concentration: LCL Tested Dilution: RTU Diluent: None					
Soil load		5% FBS					
Carrier type, # per lot		Glass Petri dishes (100 x 15 mm); 1 carrier per lot					
Test conditions		**Contact time**	10 minutes	**Temp**	22.0 °C	**RH**	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Relative Humidity was not provided					

4.	**MRID**	51683404	**Study Completion Date:**	April 30, 2021
Study Objective		Wetness Determination Test		
Testing Lab, Lab Study ID		Lonza, LLC; Project # CM211012W-CPI		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Not applicable (N/a)		
Indicator Cell Culture		Not applicable (N/a)		
Test Method		Gravimetric and Physical Wetness Determination Test; Protocol # LZ01080719.CPV		
Application Method		For each lot tested, around 700 mL volume of liquid test substance was transferred into Victory Innovation Electrostatic Sprayer for use in testing. Test Device: Victory Innovation cordless Electrostatic handheld Sprayer Model Number: H202092290 Droplet size: 80 micron 8 inches minimum and 1 foot maximum, at a 45 degree angle for 5 seconds		
	Name/ID	Nugen EHP-RTU		
	Lots	Lot 6111-004: 1.22% Hydrogen Peroxide		

Test Substance Preparation	**☐ 1 ☒ 2 ☐ 3**	Lot 6111-005A: 1.22% Hydrogen Peroxide					
	Preparation	Tested concentration: Nominal Tested Dilution: RTU Diluent: None					
Soil load		5% FBS					
Carrier type, # per lot		Glass Petri dishes (100 x 15 mm); 3 carriers per lot/ per Spray Distance					
Test conditions		**Contact time**	3 minutes	**Temp**	22.0 °C	**RH**	35.0-37.0%
Neutralizer		Not applicable (N/a)					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		None					

5.	**MRID**	51683405		
Study Objective		Confirmatory Disinfection for ESS – bactericidal		
Study Title		AOAC Germicidal Spray Test using Electrostatic Spray Application		
Testing Lab; Lab Study ID		Lonza LLC; Project# CM211012-CPI		
Experimental Start Date		--	**Study Completion Date:**	April 30, 2021
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		*Pseudomonas aeruginosa* (ATCC 15442) *Staphylococcus aureus* (ATCC 6538)		
Test Method		Association of Official Analytical Chemists, International." AOAC Official Method 961.02. Germicidal Spray Products as Disinfectants. Revised 2013.		
Application Method		Test Device: Victory Innovation cordless Electrostatic handheld Sprayer Model Number: H202092290 Droplet size: 80 micron 8 inches minimum and 1 foot maximum, at a 45 degree angle for 5 seconds		
Test Substance Preparation	**Name/ID**	Nugen EHP-RTU		
	Lots **☐ 1 ☒ 2 ☐ 3**	Lot 6111-004; 1.22% Hydrogen Peroxide Lot 6111-005A; 1.22% Hydrogen Peroxide		
	Preparation	Tested concentration: Nominal Tested Dilution: RTU Diluent: None		
Soil load		5% FBS		
Carrier type, # per lot		25 mm x 25 mm glass slides; 10 carriers/lot/distance		
Test conditions		Contact time: 3 minutes Temperature: 19.9-20.4◦C Relative humidity: 30% - 57%		
Neutralizer		Letheen broth + 0.07% Lecithin + 0.5% Tween 80 + 0.1% Catalase		
Incubation Conditions		48 ± 2 h at 35-37 ◦C		
Reviewer comments		None		

(i.e. protocol deviations and amendments, retesting, control failures, etc.)	

6.	**MRID**	51683406		
Study Objective		Confirmatory Disinfection for ESS – virucidal		
Study Title		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces utilizing an Electrostatic Spray Device		
Testing Lab; Lab Study ID		Lonza Specialty Ingredients Microbiology Center of Excellence Innovation and Technology Center Alpharetta, GA; CM211012V-CPI		
Experimental Start Date		--	**Study Completion Date:**	May 18, 2021
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Feline Calicivirus (FCV), Strain: F9, ATCC VR-782		
Indicator Cell Cultures		Crandell-Rees Feline Kidney (CRFK) cells (ATCC CCL-94)		
Test Method		ASTM E1053-20, Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces, ASTM International, West Conshohocken, PA, 2020.		
Application Method		Test Device: Victory Innovation cordless Electrostatic handheld Sprayer Model Number: H202092290 Droplet size: 80 micron 8 inches minimum and 1 foot maximum, at a 45 degree angle for 5 seconds		
Test Substance Preparation	**Name/ID**	Nugen EHP-RTU		
	Lots **☐ 1 ☒ 2 ☐ 3**	Lot 6111-004; 1.22% Hydrogen Peroxide Lot 6111-005A; 1.22% Hydrogen Peroxide		
	Preparation	Tested concentration: Nominal Tested Dilution: RTU Diluent: None		
Soil load		5% FBS		
Carrier type, # per lot		Sterile Glass Petri dish (100 mm x 15 mm); 2 carriers/lot		
Test conditions		Contact time: 3 minutes Temperature: 21.5 – 21.9°C Relative humidity: 30% - 57%		
Neutralizer		Sephadex LH-20 gel filtration		
Incubation Conditions		~7 days at 36.0 ± 2°C with 5-7% CO_2		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		None		

IV. STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results															Dried Virus Control (Average $TCID_{50}$/carrier)
			Lot 6079-148					Lot 6079-148-B					Lot 6079-150					
RTU Spray, 3 min. contact time, 5% FBS																		
51683401	Human Adenovirus type 5, Strain Adenoid 75, ATCC VR-5		*Replicates*					*Replicates*					*Replicates*					5.14
			1	*2*	*3*	*4*	*5*	*1*	*2*	*3*	*4*	*5*	*1*	*2*	*3*	*4*	*5*	
		10^{-1} dilution	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	
		10^{-2} to 10^{-8} dilution	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		Log_{10} $TCID_{50}$/carrier	≤ $10^{1.80}$					≤ $10^{1.80}$					≤ $10^{1.80}$					
		Log Reduction	≥ 3.34 log_{10}					≥ 3.34 log_{10}					≥ 3.34 log_{10}					

MRID	Organism	Description	Results		Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			Lot 6074-166	Lot 6074-167	
RTU Spray; 30 second contact time, 5% FBS					
51683402	Measles Virus, Strain: Edmontson, ATCC VR-24	10^{-2} to 10^{-3} dilution	Cytotoxicity present	Cytotoxicity present	6.10
		10^{-4} to 10^{-7} dilution	Complete Inactivation	Complete Inactivation	
		Log_{10} $TCID_{50}$/carrier	≤ 3.50	≤ 3.50	
		Log Reduction	≥ 3.00	≥ 3.00	
			Lot 6079-028	**Lot 6079-029**	
RTU Spray; 10 minute contact time, 5% FBS					
51683403	Canine Parvovirus, ATCC VR-2017, Strain Cornell	10^{-1} dilution	Cytotoxicity present	Complete Inactivation	5.30
		10^{-2} dilution	Positive for the presence of virus	Complete Inactivation	
		10^{-3} to 10^{-6} dilution	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/carrier	$10^{2.05}$	≥ $10^{0.80}$	
		Log Reduction	3.25 log_{10}	≥ 4.50 log_{10}	

ESS Confirmatory Disinfection – Bactericidal Efficacy (Test Substance: Nugen EHP-RTU)

MRID	Organism	Distance (exposure time)	No. Exhibiting Growth/Total No. Tested		Carrier Pop. (Avg Log_{10}CFU/Carrier)
RTU Spray; 3 minute contact time, 5 second spray, 5% FBS					
			Lot 6111-004	**Lot 6111-005A**	
51683405	*Pseudomonas aeruginosa* ATCC 15442	8 inches	0/10	0/10	6.38
		1 foot	0/10	0/10	
	Staphylococcus aureus ATCC 6538	8 inches	0/10	0/10	5.79
		1 foot	0/10	0/10	

ESS Confirmatory Disinfection – Virucidal Efficacy (Test Substance: Nugen EHP-RTU)

MRID	Organism	Batch	Description	Results				Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
				8 inches		1 foot		
RTU Spray; 3 minute contact time, 5 second spray, 5% FBS								
51683406	Feline Calicivirus (FCV), Strain: F9, ATCC VR-782	Lot 6111-004		Rep 1	Rep 2	Rep 1	Rep 2	8 inches (Rep 1: 6.50 log_{10} Rep 2: 7.25 log_{10}) 1 foot (Rep 1: 6.75 log_{10} Rep 2: 7.25 log_{10})
			10^{-1} to 10^{-2} dilution	TTTT	TTTT	TTTT	TTTT	
			10^{-3} to 10^{-6} dilution	0000	0000	0000	0000	
			$TCID_{50}$/carrier	≤2.50 log_{10}	≤2.50 log_{10}	≤2.50 log_{10}	≤2.50 log_{10}	
			Log Reduction	≥4.38 log_{10}	≥4.38 log_{10}	≥4.50 log_{10}	≥4.50 log_{10}	
		Lot 6111-005A		Rep 1	Rep 2	Rep 1	Rep 2	8 inches (Rep 1: 6.50 log_{10} Rep 2: 7.25 log_{10}) 1 foot (Rep 1: 6.75 log_{10}
			10^{-1} to 10^{-2} dilution	TTTT	TTTT	TTTT	TTTT	
			10^{-3} to 10^{-6} dilution	0000	0000	0000	0000	

			$TCID_{50}$/carrier	≤2.50 log_{10}	≤2.50 log_{10}	≤2.50 log_{10}	≤2.50 log_{10}	Rep 2: 7.25 log_{10})
			Log Reduction	≥4.38 log_{10}	≥4.38 log_{10}	≥4.50 log_{10}	≥4.50 log_{10}	

(T) = Cytotoxicity observed
(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present
(NT) = Not tested
(NA) = Not applicable

Wetness testing

In addition to the efficacy testing, the registrant also conducted wetness testing to demonstrate that the surface remains visibly wet over the duration of the contact time.

MRID#	Average Weight (g) for 5 sec. spray time, 3 minute exposure, RTU, 35.0- 37.0% RH & 22˚C				
	Batch	**Weight Type**	**Rep. 1**	**Rep. 2**	**Rep. 3**
51683406	**8 inches away (5 second spray time)**				
	Lot 6111-004	Weight #1 (dry untreated)	77.88g	85.00g	87.20g
		Weight #2 (wet treated)	84.56g	90.91g	93.17g
		Weight #3 (post contact time)	84.51g	90.90g	93.08g
		Remaining weight	**6.63g**	**5.90g**	**5.88g**
		Wetness Observation	Wet	Wet	Wet
	Lot 6111-005A	Weight #1 (dry untreated)	87.13g	87.64g	95.06g
		Weight #2 (wet treated)	93.23g	92.07g	100.72g
		Weight #3 (post contact time)	92.07g	92.04g	100.71g
		Remaining weight	**6.10g**	**4.40g**	**5.65g**
		Wetness Observation	Wet	Wet	Wet
	1 foot away (5 second spray time)				
	Lot 6111-004	Weight #1 (dry untreated)	86.09g	73.28g	81.38g
		Weight #2 (wet treated)	90.94g	76.84g	85.43g
		Weight #3 (post contact time)	90.93g	76.83g	85.37g
		Remaining weight	**4.84g**	**3.55g**	**3.99g**
		Wetness Observation	Wet	Wet	Wet
	Lot 6111-005A	Weight #1 (dry untreated)	81.89g	82.92g	94.18g
		Weight #2 (wet treated)	85.60g	86.91g	97.82g
		Weight #3 (post contact time)	85.59g	86.90g	97.80g
		Remaining weight	**3.70g**	**3.98g**	**3.62g**
		Wetness Observation	Wet	Wet	Wet

V. STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51683401	Disinfectant, virucidal	Hard, non-porous surfaces	RTU spray	3 minutes	5% FBS	None	• Human Adenovirus type 5	**Yes**
51683402	Disinfectant, virucidal	Hard, non-porous surfaces	RTU spray	30 seconds	5% FBS	None	• Measles Virus, Strain: Edmontson, ATCC VR-24	**Yes**
51683403	Disinfectant, virucidal	Hard, non-porous surfaces	RTU spray	10 minutes	5% FBS	None	• Canine Parvovirus, ATCC VR-2017, Strain Cornell	**Yes**
51683405	Disinfectant, Bactericidal activity Electrostatic Sprayer	Hard, non-porous surfaces	RTU spray; 8 in. & 1 foot	3 minutes	5% FBS	None	• *Pseudomonas aeruginosa* ATCC 15442 • *Staphylococcus aureus* ATCC 6538	**Yes**
51683406	Disinfectant, Virucidal activity Electrostatic Sprayer	Hard, non-porous surfaces	RTU spray; 8 in. & 1 foot	3 minutes	5% FBS	None	• Feline Calicivirus (FCV), Strain: F9, ATCC VR-782	**Yes**

VI. LABEL COMMENTS

Label Date/Identification Number: 2021-09-23

1. **DS-6640, EPA Reg. No. 6836-385**

   a. The proposed label claims that the product, **DS-6640**, when applied as a RTU Spray at a distance of 6-8 in. from surface**,** is an effective one-step disinfectant against Human Adenovirus type 5 on hard, non-porous surfaces for a 3-minute contact time:

      This claim is **acceptable** as it is supported by the submitted data. In future testing, the laboratory should report the relative humidity during testing.

   b. The proposed label claims that the product, **DS-6640**, when applied as a RTU Spray at a distance of 6-8 in. from surface**,** is an effective one-step disinfectant against Measles Virus on hard, non-porous surfaces for a 30 second contact time:

      This claim is **acceptable** as it is supported by the submitted data.

   c. The proposed label claims that the product, **DS-6640**, when applied as a RTU Spray at a distance of 6-8 in. from surface**,** is an effective one-step disinfectant against Canine Parvovirus on hard, non-porous surfaces for a 10-minute contact time:

      This claim is **acceptable** as it is supported by the submitted data. In future testing, the laboratory should report the relative humidity during testing.

   d. The proposed label claims that the RTU spray product, DS-6640, when used with an electrostatic sprayer as directed from 8 inches to 1 foot distance on hard, non-porous surfaces for a 3-minute contact time is an effective one-step disinfectant against the following organisms:

      Pseudomonas aeruginosa (ATCC 15442)
      Staphylococcus aureus (ATCC 6538)
      Feline calicivirus Strain: F9 (ATCC VR-782)

      These claims are **acceptable** as they are supported by the submitted data. For future testing, please include the experimental start date in study reports. The following revisions should be made to the electrostatic sprayer application use-directions on page 10 of 14:

      - The directions should specify effectiveness against bacteria and viruses that the product has shown effectiveness against at 3-minute contact time. A disclaimer should be added to specify that product is not for use to treat surfaces against Canine Parvovirus as this organism is considered hardest to kill based on size out of the viruses tested. The directions for use should also exclude sanitization.
      - If applicable, specify that end-users should consult the user manual for the specific electrostatic sprayer that is being used

2. **DS-6809, EPA Reg. No. 6836-388**

    a. The proposed label claims that the product, **DS-6809**, when applied as a RTU towelette**,** is an effective one-step disinfectant against Human Adenovirus type 5 on hard, non-porous surfaces for a 3-minute contact time:

    This claim is **acceptable** as it is supported by the submitted data.

    b. The proposed label claims that the product, **DS-6809**, when applied as a RTU towelette**,** is an effective one-step disinfectant against Measles Virus on hard, non-porous surfaces for a 30 second contact time:

    This claim is **acceptable** as it is supported by the submitted data.

3. Make the following change to all three proposed labels:

DS-6640, EPA Reg. No. 6836-385

a. Throughout the label,
    i. Under marketing claims, qualify all 3 minute disinfection claims with “except for canine parvovirus” or something similar since the contact time for this organism is 10 minutes.
b. On page 2,
    i. Recommend remove or revise “fights” in disinfection claims as this term is implies heightened efficacy.
    ii. Qualify “environmental surfaces” with hard, non-porous.
    iii. Specify the surface material (i.e., hard, non-porous) to be treated under Sanitization Claims. The current claims are too ambiguous as to what type of surfaces should be treated.
c. On page 4, recommend associating the appropriate contact times with the organism names. Add the strain source to SARS-CoV-2 without including the region.
d. On page 9, revise heavily soiled and heavy soil to read visibly soiled and visible soils in the following use directions:
    i. “For heavily soiled instruments and tools, a preliminary…”
    ii. “Remove all heavy soils prior to application.”
e. On page 10, in the electrostatic sprayer use directions,
    i. Revise “Clean visibly dirty surfaces prior to spraying.” To read “Clean visibly soiled surfaces prior to spraying.”

DS-6809, EPA Reg. No. 6836-388

a. Throughout the label,
    i. When claims reference effectiveness in use locations (e.g., households, kitchen, bathroom, all over/around the house/home, any room etc.), specify applicable surfaces that the product is intended to be used on hard, non-porous. Overly broad language may imply use beyond hard, nonporous surfaces which is misleading for end users.
    ii. Remove references to locations and regions when describing organism strains, such as “Brazil” & “Hong Kong”.
b. On page 5, remove the Bacteriostatic claims section. Data was not submitted to support 24-hour bacterial prevention claims.

c. On page 9,
    i. Remove references to the “[stomach flu virus] and [cause of the stomach flu]” as this condition is too vague. Additionally, broad illness and disease claims are not permitted on antimicrobial pesticide labels.
    ii. Remove “a common cause of food borne illness” as this is too vague. Additionally, claims that reference food poisoning should have the specific organism listed in the claims, not qualified as a footnote.
    iii. Remove the claim, “[Quick[ly]] [Fast-Acting] [One-Step] Clean[s] [Cleaning] and Disinfect[s][Disinfection][Disinfectant] [Wipe] [in one easy step]4” as this is misleading. Fast acting claims are only appropriate when contact times are 30 or less seconds. None of the approved organisms for disinfection meet this criteria.
d. On page 10, remove “The scrubbing [power][side] of a sponge in a disinfecting wipe” as this implies heightened efficacy of the product in reference to disinfection.
e. On page 10, specify the surface material (i.e., hard, non-porous) to be treated under Sanitization Claims. The current claims are too ambiguous as to what type of surfaces should be treated.
f. On page 11 (and throughout the label), qualify “household bacteria” with the list of relevant organisms as the agency does not have a definition for this term.
g. On page 17, associate the appropriate contact times with the organism names. Add the strain source to SARS-CoV-2 without including the region.
h. On page 22, remove the instruction for bacteriostatic use as the wording implies effectiveness as residual efficacy against bacteria for 24 hours.
i. Remove brackets from “enterica” in footnote #9.